REMARKS

Claims 9-12 are pending in the instant application. Claims 9-12 have been rejected. Claim 9 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §112

Claims 9-12 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not disclosed in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention has been maintained. The Examiner suggests that the specification does not provide support for a promoter which is regulated by TGF-β, activin, or bone morphogenetic protein signal. It is further suggested that the specification does not exemplify the claimed method or experimental design.

Claims 9-12 have been further rejected under 35 U.S.C. 112, second paragraph, as being indefinite for reciting a "bone morphogenetic protein signal." It is suggested that it is not clear what this signal is and how it regulates the promoter.

Applicant respectfully disagrees with these rejections.

MPEP 2163.02 indicates that an objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the

written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). Accordingly, the specification must reasonably convey the inventive subject matter. In this regard, pages 14-15 describe the essential elements of the claimed assay, namely, co-expression of a Smad protein, a DNA-binding Smad co-repressor protein and a CtBP protein in a cell and use of a TGF-β-dependent reporter construct in the cell to determine whether a test compound prevents protein-protein interactions required for repression of transcription from genes induced by TGF-β, activin or bone morphogenetic protein signaling. In the context of the teachings of the specification as a whole, the claimed method and its elements are clearly described.

In particular, page 7 (lines 8-15) clearly discloses that the present invention

> "relates to methods for screening and testing of compounds that interfere with TGFβ-dependent transcriptional repression in mammalian cells, and in cells of model organisms such as Drosophila. The screening and testing methods are based on the finding that the Drosophila Smad proteins, Mad and Medea, are able to interact directly with the co-repressor protein CtBP through the Smad MH1 domain.

> This was unexpected since the MH1 domain of these Smad proteins is known to lack a CtBP interaction motif or binding site. A Drosophila DNA-binding Smad co-repressor, Schnurri, has also been shown to interact both with Mad and with CtBP."

This interaction and its use in a screening assay is found in the disclosure at pages 9 and 10 which demonstrate co-expressing a Smad protein (*i.e.*, Mad and Medea), a DNA-binding Smad co-repressor protein (*i.e.*, Schnurri) and a CtBP protein (*i.e.*, dCtBP) in a cell (*i.e.*, Drosophila S2 cells) and detecting the level of transcription of a reporter (*i.e.*, LacZ) with a promoter (*i.e.*, a promoter containing a sequence from the wingless disc enhancer region (SEQ ID NO:5)) in the presence of a test compound (*i.e.*, Ci transcription factor). See also Figure 6. Accordingly, in an earnest effort to highlight a distinguishing characteristic of the promoter employed in the instant assay and place the claims condition for allowance, Applicant has amended claim 9, removing reference to a promoter which is regulated by a TGF-β, activin or bone morphogenetic protein signal, and indicating that the promoter has the response element TAGCCTGCCGTCGCGATTCGACAACTTTGGCCGGCACGTTGGCGAGTGTGCCATGCATGCTGATG A (SEQ ID NO:5). Support for this amendment is found in the whole of the disclosure, in particular pages 9 and 10 and Example 1 at page 15. In light of this amendment and accompanying remarks, Applicant respectfully believes that the written description requirement is clearly met. It is therefore respectfully requested that the rejections under 35 U.S.C. 112, first and second paragraphs, be reconsidered and withdrawn.

II. Conclusion

Applicant believes that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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